REMARKS

Claims 1-3, 6, 7, 10 and 12-16 have been rejected. No claims have been allowed. Claim 1 and 13 are currently amended. Claims 15 and 16 are cancelled. Claims 1-3, 6, 7, 10 and 12-14 are pending in the application.

Claim 13 has been amended to correct a typographical error. Claim 1 has been amended to include a sealing means, such as an o-ring 25, upon the sampling wand 17. Claim 1 has been amended such that the analysis structure 30 comprises a chamber 40 having a proximal end into which the sampling wand 27 is inserted to make a sealing fit around the sealing means as the sampling wand 17 moves through the chamber 40. Intermediate the proximal end and the distal end of the chamber 40 in the analysis structure 30 is a moveable open base 54 (see Figure 4) with an integral member (such as piercing member 53) of the analysis structure 30 against which the sampling swab 27 advances so as to collect the sample within a cavity 45 in a reaction well 36 at a distal end of the analysis structure 30. Support for the sampling wand 17 with an a sampling swab 27, and a sealing means as an o-ring 25 upon the sampling wand 17 having a sealing fit to inner chamber 40 of sampling/analysis member 15 is found in paragraph 0050 in the specification. Support for the o-ring 25

providing a sealing fit between the wand 17 and the inner chamber 40 as the wand 17 moves longitudinally through the inner chamber 40 is found in paragraph 0050, 0052 and 0053 in the specification. Support for a moveable open base 54 of the analysis structure 30 against which the sampling swab advances is found in paragraphs 0054 and 0056 and seen in Figures 4, 5 and 9. Support for collecting the sample in a reaction well 36 to contact a reagent disc 48 is found at paragraph 0065 in the specification. Support for the reagent disc cavity 45 in the reaction well 36 is found in paragraphs 0051, 0055 and 0066 in the specification. An illustration of a sampling swab 27 advanced up against a base 54 towards a reagent disc 48 in a reagent disc cavity 45 is seen in Figure 9. The porous non-fibrous absorbant polymeric material enables the device to provide the sensitivity necessary for the assay. Each of the following Claims depend upon Claim 1 and incorporate each of these limitations.

Claim Rejections

(1.) Claims 1, 3, 6, 7, and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aronowitz (U.S. Patent Application Publication No. 2001/0008614) in view of Kinoshita *et al.* (U.S. Patent No. 5,728,350).

Aronowitz discloses a sample collection system having a collector 118 such as a sponge attached to a cap 114. The collector 118 is used to collect a sample which is then placed within a recovery container 116. The recovery container 116 is placed in a collection tube 112. The recovery container 116 preferably is constructed with a flexible sidewall which is capable of being finger squeezed to release the sample through one or more apertures 120 in the container into the collection tube 112.

Kinoshita *et al.* discloses a chemical or microbiological test kit with a support 13 having a sample-receiving part 11, which can be a polymer such as polyvinyl alcohol, upon the support 13. Kinoshita *et al.* further teach that the kit can have a reagent-containing part 12 which, prior to using the test kit, has been impregnated with a reagent solution and then dried.

Neither Aronowitz or Kinoshita *et al.* taken alone or in combination, show or suggest an analysis structure

having a chamber with a proximal end into which the sampling wand is inserted to make a sealing fit around the sealing means as the wand moves through the chamber. Nor do Aronowitz or Kinoshita *et al.* show or suggest a base intermediate the distal and proximal ends of the analysis structure against which the sampling swab 27 advances to remove the sample and collect the sample within a cavity 45 in a reaction well 36. In some embodiments, as described in paragraph 0059 of the specification, the sampling swab 27 preferably can hold 100-125 µL of liquid when maximally loaded. Therefore, it is important that any liquid which is used to assay for the analyte of interest in the claimed sampling/analysis member 15 is collected into the reagent disc 48 to detect the presence of the analyte of interest in the sample.

Each of the new limitations in the amended Claims are directed to structures which when working together allow for the collection of the sample into the cavity 45 in the reaction well 36 so as to enter the reagent disc 48. Since even small droplets upon the wall of the chamber can add up to be a considerable portion of the volume of sample in the sampling swab 27, the efficient collection of the sample into the cavity 45 improves the likelihood that a low concentration of analyte of interest in the sample will be

detected. The sealing means, such as the o-ring 25, provides a sealing fit within the chamber, such as inner chamber 40 of the analysis structure. This fit provides a squeegee type of action, so that any droplets on the walls of the chamber 40 are moved towards the distal end of the chamber 40 to collect in the reaction well 36. Once the sampling swab 27 has been inserted in the inner chamber 40 far enough, the sampling swab 27 will press against the base 54 as it is advanced towards the distal end. This squeezes the sampling swab 27 so that more sample volume is collected into the cavity 45. The sample volume is collected into a cavity 45 with the reagent disc 48, so that the sample volume is physically close to the reagent disc 48, so that the entire volume in the cavity 45 is absorbed into the reagent disc 48. In this manner, the volume of sample is collected into the porous, non-fibrous polymeric reagent disc 48, where it can be in contact with the dried reagents to be assayed.

It is an object of the present invention to provide a simple and effective method of collecting a sample which can be done on-site by untrained workers in locations such as slaughterhouses and food handling facilities (See paragraphs 0003 and 0006 in the specification). The present invention would be used in locations would not have

laboratory equipment available, such as centrifuges. Additionally, the worker taking the samples in these locations would not likely have the skill and experience to have proper pipetting technique, so avoiding laborious and time consuming procedures such as pipetting is critical (See paragraph 0012 in the specification).

Neither Aronowitz or Kinoshita *et al.* taken alone or in combination, show or suggest the claimed sample/analysis member having the simple and effective system of collecting the sample into the reagent disc. For example, Kinoshita *et al.* teach direct application of a sample to the sample-receiving parts (*See eg.* Kinoshita *et al.*: col. 8, lines 4-6). Aronowitz illustrates a collection system 510 used with an external test station 560 in Figure 5. In this arrangement, the sample aliquot is passed from the collector 518 by either finger squeezing or centrifugation (Aronowitz: paragraph 0096). Then the closed end 512C of the collection tube 512 is brought into close association with the test station 560 to apply an aliquot of the sample to the testing station 560. This is accomplished by inserting prong 526 into the collection tube 512 via channel 520 to access the sample. The aliquot of the sample must then be applied onto the test disk 575 for the reaction to proceed. Finger squeezing the collector 518 is

not as effective to remove the entire volume of sample, and centrifugation requires the use of a centrifuge to remove the sample. Furthermore, the worker taking the sample must carefully transfer the aliquot of sample to the test disk 575 without spilling it. In light of the above amendments and arguments, the currently claimed invention is patentable over Aronowitz, and Kinoshita *et al.* either taken alone or in combination. Reconsideration of the rejection is requested.

(2.) Claims 2 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aronowitz (U.S. Patent Application Publication No. 2001/0008614) in view of Kinoshita *et al.* (U.S. Patent No. 5,728,350), and further in view of Rosenblatt (U.S. Patent No. 4,098,728).

Aronowitz and Kinoshita *et al.* were discussed above. In addition, Rosenblatt discloses a polyvinyl alcohol porous material useful as a medical sponge. None of the cited prior art references show or suggest the claimed sample/analysis member having the simple and effective system of collecting the sample into the reagent disc. Neither Aronowitz, Kinoshita *et al.* or Rosenblatt taken alone or in combination, show or suggest an analysis structure having a chamber with a proximal end into which

the sampling wand is inserted to make a sealing fit around the sealing means as the wand moves through the chamber. Aronowitz, Kinoshita *et al.* or Rosenblatt do not show or suggest a distal end having a moveable open base of the analysis structure against which the sampling swab advances to collect the sample within a cavity in a reaction well. In light of these amendments and the arguments of the previous section, the currently claimed invention is patentable over Aronowitz, Kinoshita *et al.* and Rosenblatt, either taken alone or in combination. Reconsideration of the rejection is requested.

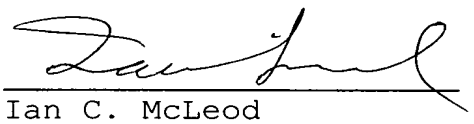
(3.) Claims 13-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Aronowitz (U.S. Patent Application Publication No. 2001/0008614) in view of Kinoshita *et al.* (U.S. Patent No. 5,728,350), and further in view of Miller *et al.* (U.S. Patent No. 5,736,351).

Claim 16 is cancelled. In regards to Claims 13-15, Aronowitz and Kinoshita *et al.* were discussed above. In addition, Miller *et al.* teach a luciferin-luciferase substrate which reacts with adenosine triphosphate (ATP) to generate chemiluminescence. Various devices are disclosed to conduct the assay, none of which are similar to the claimed invention. None of the cited prior art references

show or suggest the claimed sample/analysis member having the simple and effective system of collecting the sample into the porous, non-fibrous polymeric reagent disc of Claims 13-14 and 16. Neither Aronowitz, Kinoshita *et al.* or Miller *et al.* taken alone or in combination, show or suggest an analysis structure having a chamber with a proximal end into which the sampling wand is inserted to make a sealing fit around the sealing means as the wand moves through the chamber. Aronowitz, Kinoshita *et al.* or Miller *et al.* do not show or suggest a moveable open base intermediate a distal end and a proximal end of the analysis structure against which the sampling swab advances to collect the sample within a cavity at a distal end of the analysis structure in a reaction well. In light of the these amendments and arguments of the previous section, the currently claimed invention is patentable over Aronowitz, Kinoshita *et al.* or Miller *et al.*, either taken alone or in combination. Reconsideration of the rejection is requested.

The cited references do not show or suggest all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 1-3, 6, 7, 10 and 12-14 are patentable and in condition suitable for allowance. Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully,



Ian C. McLeod
Registration No. 20,931

McLEOD & MOYNE, P.C.
2190 Commons Parkway
Okemos, Michigan 48864

Telephone: (517) 347-4100
Facsimile: (517) 347-4103